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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,387	01/22/2004	Dennis M. Vigil	12013/47103	2425

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WASHINGTON, DC 20005

EXAMINER

MCCORKLE, MELISSA A

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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06/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/761,387

Applicant(s)

VIGIL ET AL.

Examiner

Melissa A. McCorkle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Double Patenting

This double patenting rejection is being repeated due to the fact that the Terminal Disclaimer filed on 01/30/2007 was disapproved.

1. Claims 1-4, 7, 9-10, 12-14, 17, 19-23, 26 & 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 8, 10, 12-14, 16, 18, 20-23, 25, 27 of U.S. Patent No. 6,695,830. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims would be obvious over the currently pending claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 4, 10, 12, 14, 20, 21 are 23 are rejected under 35 U.S.C. 102(b) as being anticipated by March et al (5,306,250.) March discloses a method for releasing fluid medicaments into a vessel wall of a patient at a treatment site, the method comprising the steps of providing an expanding member 46 defining an axis and having a plurality of dispensers 48 mounted on said expanding member for movement therewith, said dispensers consisting only of dispensers positioned in a single plane oriented substantially perpendicular to said axis [fig 7]; advancing said expanding member through the vessel to the site; moving said expanding member between a first

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configuration [fig 2] wherein said dispensers are positioned substantially adjacent of said expanding member, and a second configuration [fig 3] wherein said dispensers are radially extended from said axis penetrating into the vessel wall; and providing a fluid medicament and releasing said fluid medicament through said dispensers into the vessel wall for substantially circumferential dispersion of said fluid medicament into said vessel wall [column 5 line 55 – col 6 line 54, and claim 1; furthermore it is inherent to provide an object if all structural limitations are met];

4. wherein said fluid medicament inhibits the proliferation of smooth tissue growth in the vessel [col1 line 35, furthermore since all structural limitations are met it is inherent that the device will function as claimed];

5. wherein said fluid medicament stimulates the production of collateral vessels [col 1 line 30, furthermore since all structural limitations are met it is inherent that the device will function as claimed].

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 3, 13, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over March et al in view of Wilcox et al (5,681,289.) March discloses all of applicant's basic inventive concept of a method of delivering medication into an arterial wall with the exception of the fluid medicament comprising a radioactive isotope. Wilcox shows this feature to be old in the medical delivery devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use a radioactive isotope in the delivery device for the well-known purpose of providing for infection and pain control (column 1 lines 15).
9. Claims 7, 9, 17, 19, 26, & 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over March in view of Nabel et al (5,328,470.) March discloses all of applicant's basic inventive concept of a method of delivery medication into an arterial wall with the exception of the fluid medicament comprising a binder which binds to at least a portion of the vessel wall, or wherein said fluid medicament comprises a gene for gene therapy. Nabel shows these features to be old in the medical delivery devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to have the medicament comprise a gene or a binder for the purpose of treating the specific diseases that these medicaments treat [see col 8 lines 8-46].

Response to Arguments

1. Applicant's arguments filed 01/30/2007 have been fully considered but they are not persuasive. Regarding the use of the March and March in view of Nabel reference,

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applicant argues that none of the catheter assemblies in March are shown to have the microapertures positioned in only a single plane...however, the claim reads "being positioned in a plane oriented substantially perpendicular to said axis." Examiner points out that any dispenser located on March is positioned in "a plane perpendicular to said axis." There is not claim language requiring the dispensers to be positioned in a *single plane*. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

2. Regarding Applicant's arguments of using the Wilcox as a teaching reference, Examiner respectfully disagrees that Wilcox does not teach the use of radioactive isotopes in association with any of the medical devices. He clearly teaches this use is common in the art, and further describes the use as old in the art at column 1 lines 31-35, where he describes the devices and procedures of the invention can be used for many different functions, including infection control, which he describes at line 15-17 as using a radioactive isotope for infection control. He discloses delivering a range of agents, including radioactive isotope, through a connecting line from a reservoir.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Melissa A McCorkle

10/10/2010 10:00 AM
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3763